

Notice of Allowability

Application No.

09/619,901

Examiner

Catherine S. Williams

Applicant(s)

BOTICH ET AL.

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/3/06.
2. ☒ The allowed claim(s) is/are 45,46,48-52 and 54-75.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stephen Eland on 3/8/06.

The application has been amended as follows:

In the claims:

In claim 45 (Amended) line 18 after "rearwardly when" and before "the", --the needle is disposed in the projecting position and while—has been added.

In claim 45 (Amended) line 19 "separate from" has been replaced with --not attached to--.

In claim 50 line 3-4 "after the plunger is displaced into the terminal position—has been cancelled.

In claim 51 (Amended) line 6 after "forward position" and before "to provide", --adjacent the forward end of the barrel—has been added.

In claim 51 (Amended) between lines 15 and 16 --wherein the housing is configured so that the biasing element is operable to bias the needle rearwardly when the needle is disposed in the projecting position and while the housing is not connected to the hollow barrel;—has been inserted.

In claim 56 line 3-4 "after the plunger is displaced forwardly—has been cancelled.

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In claim 57 line 4 after “connector” and before the comma “,”, --at a forward end—has been inserted.

In claim 57 line 12 “housing” has been replaced with --second connector--.

In claim 57 line 13 after “rearwardly” and before the semi-colon “;”, --both before and after the step of releasably connecting—has been added.

In claim 57 line 17 after “plunger” and before the semi-colon “;”, --after the plunger is adjacent the forward end of the housing—has been added.

In claim 57 line 19 after “plunger” and before the period “.”, --while the first and second connectors remain connected—has been inserted.

In claim 63 (Amended) line 3 after “connector” and before the comma “,”, --at a forward end—has been inserted.

In claim 63 (Amended) line 11 after “rearwardly” and before the semi-colon “;”, --both before and after the connecting step—has been inserted.

In claim 63 (Amended) line 10 after “while” and before “the spring”, --the forward tip of the needle projects forwardly from the hub—has been inserted.

In claim 63 (Amended) line 11 after “rearwardly” and before the comma “,”, --both before and after the step of connecting—has been inserted.

In claim 63 (Amended) line 15 after “cavity” and before the semi-colon “;”, --after the plunger is adjacent the forward end of the housing—has been added.

In claim 69 (Amended) lines 22-23 “during displacement of the plunger to displace fluid through the needle” has been replaced with --when the needle is disposed in the projecting position and while the needle assembly is not attached to the barrel--.

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In claim 69 (Amended) line 25 after “plunger” and before “causes”, --after the plunger is adjacent the forward end of the barrel—has been inserted.

In claim 69 (Amended) line 25 after “causes” and before “the”, --both—has been inserted.

Double Patenting

All previous double patenting rejections have been withdrawn in light of the amendments to the claims. The terminal disclaimer filed 3/2/04, while never officially entered, has been obviated by the amendments to the claims.

Allowable Subject Matter

Claims 45-46, 48-52 and 54-75 are allowed.

The following is an examiner's statement of reasons for allowance:

Regarding claim 45, the prior art does not teach a medical device that includes, among all the elements, a hollow barrel, a needle assembly including a needle, a hub having a cavity and a biasing element and a plunger including an internal cavity with a cover for receiving the sharpened tip of the needle in combination with the needle assembly being configured so that the biasing element is operable to bias the needle rearwardly when the needle is disposed in the projecting position and while the needle assembly is not attached to the hollow barrel, and upon pushing a rearward end of the plunger forwardly after the plunger is in the terminal position the cover of the plunger is removed from the end of the plunger where the connection between the

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needle assembly and the barrel retains the hub in a substantially fixed axial position relative to the barrel during retraction of the needle into the cavity of the plunger.

Regarding claim 51, the prior art does not teach a medical device that includes, among all the limitations, a hollow barrel, a housing including a portion of a needle and a biasing element and a plunger including an internal cavity with a cover for receiving the needle in combination with the housing being configured so that the biasing element is operable to bias the needle rearwardly when the needle is disposed in the projecting position and while the housing is not attached to the hollow barrel and upon pushing a rearward end of the plunger forwardly after the plunger is in the forward position the cover of the plunger is removed from the end of the plunger where the connection between the housing and the barrel retains the housing in a fixed axial position relative to the barrel during retraction of the needle into the cavity of the plunger.

Regarding claim 57, the prior art does not teach a method for injecting fluid that includes, among all the limitations, a hollow housing, a needle, a spring and a plunger including an internal cavity with a cover for receiving the needle in combination with the housing being configured so that the spring is operable to bias the needle rearwardly when the needle is disposed in the projecting position and while the housing is not attached to the hollow barrel, and upon pushing a rearward end of the plunger forwardly after the plunger is in the forward position the cover of the plunger is removed from the end of the plunger where the connection between the first and second connector retains the second connector in a fixed axial position relative to the housing during retraction of the needle into the cavity of the plunger.

Regarding claim 63, the prior art does not teach a method for injecting a fluid that includes, among all the limitations, a hollow housing, a needle with hub, a spring and a plunger

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including an internal cavity in combination with the housing being configured so that the spring is operable to bias the needle rearwardly when the needle is disposed in the projecting position and both before and after the hub has been connected to the housing, and upon pushing a rearward end of the plunger forwardly after the plunger is adjacent the forward end of the housing the cover of the plunger is severed and the connection between the hub is in a fixed axial position relative to the housing during retraction of the needle into the cavity of the plunger.

Regarding claim 69, the prior art does not teach a medical device that includes, among all the limitations, a barrel, a needle assembly with a base and a needle, a plunger with an internal cavity with a cover, and a biasing element in combination with the biasing element being disposed within the base and being operable to bias the needle rearwardly when the needle is disposed in the projecting position and while the needle assembly is not attached to the barrel and wherein pushing forwardly upon a rearward end of the plunger after the plunger is adjacent the forward end of the barrel causes both the cover to be removed and the needle to be released and the connection between the barrel and the needle assembly operates to retain the base in a fixed position relative to the barrel during retraction of the needle after the cover has been removed.

The prior art most similar is to Allard (USPN 4,838,869) and Kulli (USPN 4,927,414). Allard discloses a syringe that retracts a used needle into the cavity of the plunger after use. However, Allard does not teach a needle assembly that is configured so that the biasing element/spring biases the needle rearwardly while the needle is in the projecting position even when the needle assembly is not attached to the barrel. If one were to remove the needle assembly of Allard so that the needle assembly and barrel were not attached, the needle would

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not be maintained in the projecting position because the spring would retract the needle since the restraining mechanism to keep the needle in a projecting position is contained in the barrel and not the needle assembly. See figure 5. There is no motivation for incorporating the restraining mechanism into the needle assembly since the plunger must be able to contact the restraining mechanism in order for the device to function properly.

Kulli discloses a syringe with a safety retracting needle that includes a needle assembly that could maintain the needle in a projecting position while the needle assembly and barrel are not connected. The device also includes a plunger with a cavity for receiving the retracted needle. However, Kulli does not teach a plunger having a cover or a portion that can be severed. Even if one adds a cover or severing portion to the plunger of Kulli the cover or severing portion will be removed or severed when the plunger is advanced through element 20 at the proximal end of the barrel. See figure 1. This action does not meet the claim limitation of "upon pushing a rearward end of the plunger forwardly after the plunger is in the terminal/forward position, the cover of the plunger is removed" (claims 45 and 51); "removing the cover from an end of the plunger after the plunger is adjacent the forward end of the housing" (claim 57); "severing a portion of the plunger to provide access to the cavity after the plunger is adjacent the forward end of the housing" (claim 63); and "wherein pushing forwardly upon a rearward end of the plunger after the plunger is adjacent the forward end of the barrel causes both the cover of the plunger to be removed from the forward end of the plunger and the needle to be released from the projecting position" (claim 69). Therefore, even if one were to modify the reference, the prior art would not read on the claims.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams
March 20, 2006